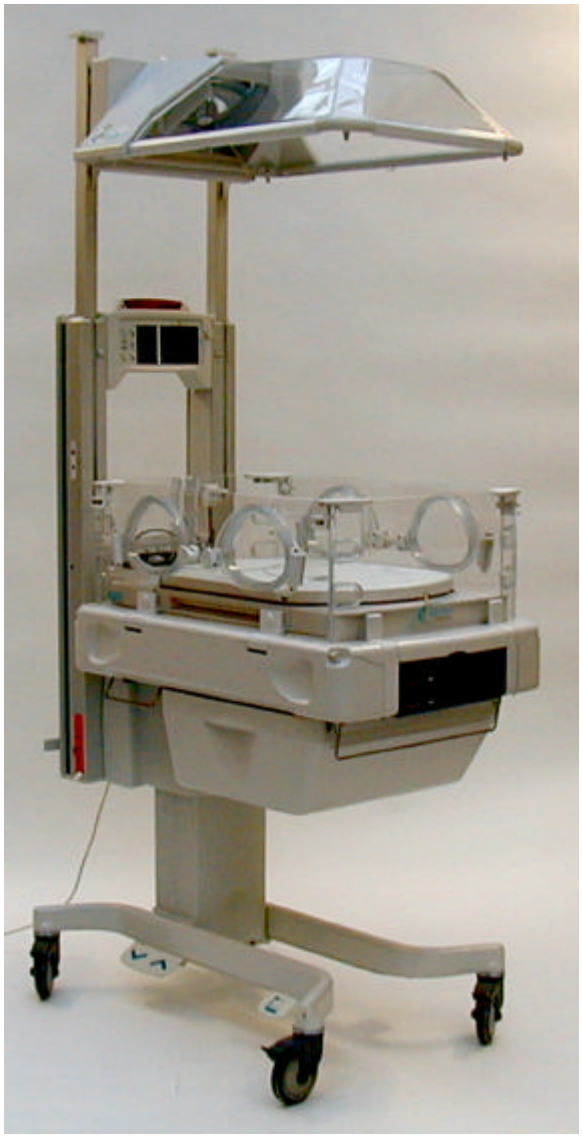
Neonatal Incubator / Infant Radiant Warmer

Ohmeda Giraffe OmniBed



Price ex VAT	£ 27,000 (basic unit) £ 29,000 (with servo O_2)
Supplier	Datex Ohmeda Ltd (see **product support** for contact information)
CE marking?	Yes
Notified Body **Manufactured to Standard?**	BSI (0086) Type tested by CSA International to IEC 60601-1, IEC 601-2-19 & IEC 601-2-21

SUMMARY

Advantages: Incubator and infant radiant warmer in one device. Relative humidity option, swivel mattress, all around access, uniform central thermal environment.

Disadvantages: Care needed on raising canopy to avoid collisions with other equipment close by. Expensive. Water reservoir difficult to open.

BRIEF DESCRIPTION

A novel device combining an incubator and a radiant warmer in one unit. The transformation from an incubator to a radiant warmer is activated by the touch of a switch. All the usual features of an incubator and radiant warmer are included. In addition the mattress swivels.

MAIN FEATURES

Incubator Mode

- Air temperature control
- Baby temperature control
- Integral humidification
- Access doors two
- Access ports up to five

Radiant Warmer Mode

- Maximum power 450W
- Manual control
- Baby temperature control

General

- Vertical height adjustment - foot-switch
- Canopy control Foot-switch (raise only)
  Finger-switch (raise and lower)
- Mattress rotates - 360°
- Electroluminescent control screen
- Four wheel locks
- X-ray tray
- Sliding storage draw
- Integral scales

Description

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DESCRIPTION

The Ohmeda Giraffe OmniBed is a novel device designed to operate as both an incubator and a radiant warmer, so reducing the necessity of transferring the patient. This mobile device incorporates all the usual features of modern incubators and radiant warmers. In incubator mode, (**Photo 1)**, it has air temperature and baby skin temperature control and integral humidification. In radiant warmer mode (**Front Cover Photo)** it has baby skin temperature control and manual heater control, where the user selects the percentage of power output from the radiant heater. The Giraffe operates **either** as an incubator or a radiant warmer, never as both simultaneously. Auditory alarms have adjustable volume and visual alarms include a large bank of red light emitting diodes (LEDs) above the control panel.

FACILITIES

Canopy: The transformation from incubator to radiant warmer mode is activated by the touch of a foot-switch, see **Photo 2** and **Photo 1,** located on the wheel base parallel to the vertical height adjustment (VHA) pedals. There are VHA and canopy foot-switches located on each side of the wheel base frame. The canopy can also be activated by a finger-switch, located each side beside the vertical rails (inset **Photo 3)**. Once the pedal or canopy up finger-switch has been pressed the canopy rises in one uninterrupted movement.

On activation using either switch the canopy immediately rises and small doors enclosing the radiant heater at the control end of the canopy start opening. When the canopy reaches its maximum height, the heater doors are fully open and the radiant heater automatically switches on.

To switch back to incubator mode the down finger-switch, marked "∨"**,** must be pressed and held to activate the lowering mechanism. If it is released the canopy will stop in mid travel. Immediately the canopy starts its descent the

Photo 1: Giraffe OmniBed in incubator mode

radiant heater switches off and the heater cover doors close.

Raising the canopy when the incubator is in servo-controlled baby mode automatically activates the radiant heater in servo-controlled baby mode using the same set temperature. Similarly if the canopy is lowered and the radiant heater was in baby mode the incubator will activate and continue to operate in baby mode.

Photo 2: Special foot pedal for raising canopy

If the Giraffe OmniBed is in air controlled mode when the canopy is raised then the radiant heater, when the canopy reaches the end of its travel, will activate in pre-warm mode and prompt the user for a manual heater power setting. When lowered in manual heater mode it will operate in air temperature mode as an incubator at the last set air temperature or at 33°C, the programmed pre-warm

temperature, and then prompt the user for a manual air temperature.

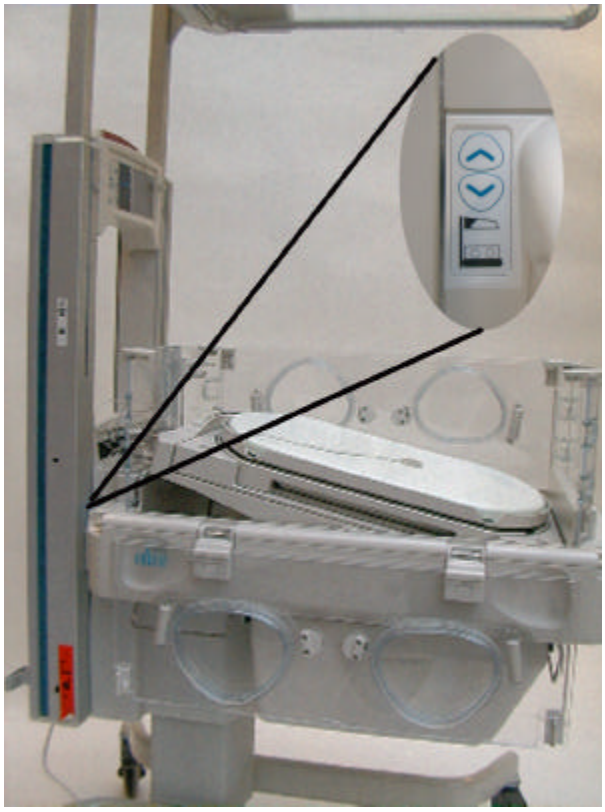


Photo 3: Access door open and mattress tilted. Inset - canopy finger switches

Patient area & bassinet: The bassinet baby compartment has four sides that can be removed individually for cleaning. Three sides can be folded down to increase patient access, the back panel, below the control panel does not fold down. This panel, on the samples we saw, had a long tubing port; the two longer sides, or access doors, have two ports each. The access doors/sides are hinged at the base and are weighted so that if they are left "unlocked" and fractionally open they move towards the closed position. Their being "unlocked" is evident from the orange flashes visible on the catches. The end panel, above the humidifier, may optionally have a hand port, a long tubing port or no ports. We saw one model with a hand port (**Photo 1**) and one with no port (**Front Cover photo**).

In incubator mode the canopy fits snugly onto the four sides allowing only the two side access doors to be folded down. The panel furthest from the controls cannot be folded down with the canopy in place. The side access doors have double walls to reduce radiant heat loss and provide a channel for the warm airflow into the incubator. These double walls may be removed for cleaning.

The mattress has staight sides but is curved at the ends giving an overall oval shape (**Photo 3)**. It has a sliding mechanism and can be withdrawn when horizontal, from either side. When withdrawn it may also be rotated about its centre, 360° rotation available, to allow better access to the neonate.

The mattress can be freely tilted to any angle up to 12° in either the feet-up or head-up direction when inside the baby compartment, (**Photo 3).** To activate the tilt a small slider, at the controls end of the mattress, is squeezed to release the tilting mechanism. The mattress is locked into position on release. Tilting the mattress with the Giraffe Omnibed in incubator mode requires the user to open a port or access door.

Vertical Height Adjustment (VHA): Foot-switches marked and **,** located on the wheel base frame, (**Photo 1)**, activate the powered height adjustment mechanism, and allow adjustment of the bassinet for user comfort, or for more comfortable access by parents sitting beside the Giraffe, for example when confined to a wheelchair. The range of travel is stated in the **Manufacturer's Data.**

Controls and Information Screen: Controls for all facilities, except the VHA and the canopy operation are located above and to the back of the bassinet in a module attached to the two upright rails see **Photo 4**. The control panel is divided into two areas, the left hand side consisting of buttons and indicators for temperature adjustment and display and the right hand side containing an electroluminescent (EL) control/information screen which displays and controls all the accessory options on the Giraffe OmniBed.

Photo 4: Control and information panel

Seven buttons, covered with a tactile membrane on the left side, allow selection of the available

Description

temperature control modes. Clockwise, starting from the top right are buttons for: baby temperature control mode (baby icon), manual heater power mode, available when operating as a radiant warmer (heater icon), air temperature control mode, available when operating as an incubator (fan icon), increased fan activation, available when operating as an incubator (open incubator and air flow icon), decrease and increase temperature setting, and , symbols respectively, and overriding the 37°C setting.

A small indicator beside each button illuminates to display which options are selected. In **Photo 4** the Giraffe is in incubator mode with air temperature control set at 34°C. The incubator indicates that the air temperature is 31.9°C and the baby's skin temperature sensor indicates a temperature of 31.4°C. The increase fan speed button has also been selected.

The EL control and information screen is activated by pressing the knob in the top right hand corner and rotating it to highlight the various options. To select an option the icon must be highlighted and then the knob pressed. Further pressing and rotation of the knob will enable selections from the menu within that option.

A help screen indicated by "**?**" gives more details on alarm conditions. Next to this a clock icon can be selected to activate a general timer which could be used for clinical procedures. An Apgar timer with associated tones is also available.

The "chart" icon accesses a menu of patient and machine monitoring information. Displays include monitoring the change in air temperature, baby temperature, heater power (if in radiant warmer mode), and relative humidity over periods of 2, 8, 24 or 96 hours. Each graphical display line can be toggled on or off using the display screen. The screen returns automatically to normal after displaying the trending information.

The "smiling face" and thermometer motif activates a procedure which on entry of patient weight, gestational age and post natal age suggests a possible air temperature range for that patient. This information is based on research published in Archives of Disease in Childhood by Sauer et al. (1984) **59** p18-22.

The "spanner" symbol accesses the setup screen allowing the user to change some basic parameters including the unit of temperature measurements, °C or °F, the volume of the alarm tones, enabling or disabling the canopy foot-switch, enabling or disabling the VHA foot-switches and the limits for manual and patient controlled alarms.

In-bed scales, if fitted, can be activated and used by selecting the "scales" icon.

Servo-controlled relative humidity can be selected, if this option is fitted, using the "three drops" icon.

Storage: A sliding storage drawer is fitted beneath the bassinet and may be accessed from either side. Additional shelves and poles may be added.

Weighing scales: Optional integral scales can be fitted beneath the mattress. The scales are operated from the EL display screen on the right hand side of the control panel, and selecting the "scales" icon accesses the in-bed scales menu. The menu software leads the user through a procedure to weigh the infant within the warming environment. The scales should be calibrated annually using the procedure described in the service manual. The patient weight data can be trended.

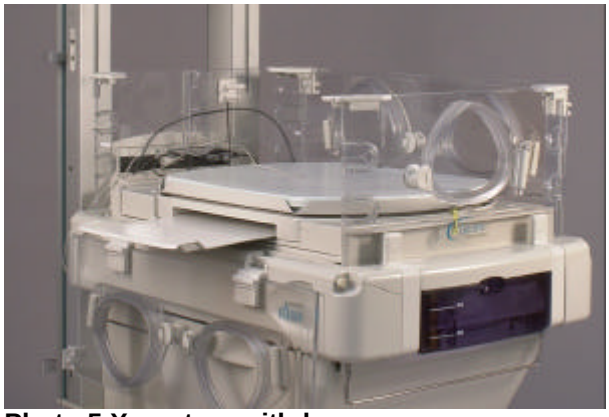


Photo 5 X-ray tray withdrawn

X-ray tray: An X-ray tray may be fitted beneath the bassinet to enable X-rays to be taken without disturbing the infant. This may be done with the canopy up or down. The tray is shown withdrawn in **Photo 5.** The scales, if installed, fit below the mattress and above the X-ray tray and have an open clear space where they coincide with the X-ray tray area. **CEDAR Note**: X-rays taken using the tray may result in a higher dose to the patient because of the bedding, the mattress and other plastics. In a previous user assessment of incubators incorporating X-ray trays or slots, ***MDA Evaluation 375***, it was discovered that users tended to prefer to place the baby directly onto the X-ray plate. From experience they had found that this resulted in clearer images and helped the radiographer to minimise the dose to the baby.

Neonatal Incubator Mode

Temperature Control: The Giraffe OmniBed temperature controls are on the left hand side of the main control panel, see **Photo 4** and **Photo 6**. Air temperature control mode is selected by pressing the air temperature control button. When switched on in incubator mode the Giraffe prompts for a "set temperature". This can be set at any value in the range 20°C to 39°C (using the overide 37°C button) in increments of 0.1°C by pressing the arrow keys as shown in **Photo 6,** here the set temperature is being increased by pressing the ^ button**.** The measured air temperature and the set air temperature (23.7°C and 33.3°C respectively in **Photo 6**) are displayed at the bottom right of the temperature control panel, the measured temperature is a larger display.

Photo 6: Control Panel - setting air temperature in incubator mode.

Baby skin temperature may also be used to control the incubator. The patient sensor should be attached to the baby as described in the manufacturer's instructions and the device switched into baby mode by pressing the "baby" icon. When baby mode has been selected, a temperature range of 35°C to 37.5°C in 0.1°C increments is available, the incubator will adjust the level of warm air to achieve this temperature.

The fan speed may be increased to enhance the air flow through the double walled side panels of the Giraffe OmniBed by pressing the Boost Air Curtain button. This extra flow of warm air is designed to help reduce heat loss and increase the rate at which the incubator achieves the set temperaure. This feature is also designed to help reduce heat loss when the access door is open, as demonstrated by the icon for activation. Once activated the fan operates at high speed for 20 minutes and then automatically switches back to normal speed, it may be manually switched back by pressing the "open incubator" icon again. **CEDAR Note**: For conditions under which the high speed fan is activated see **Manufacturer's Comments**.

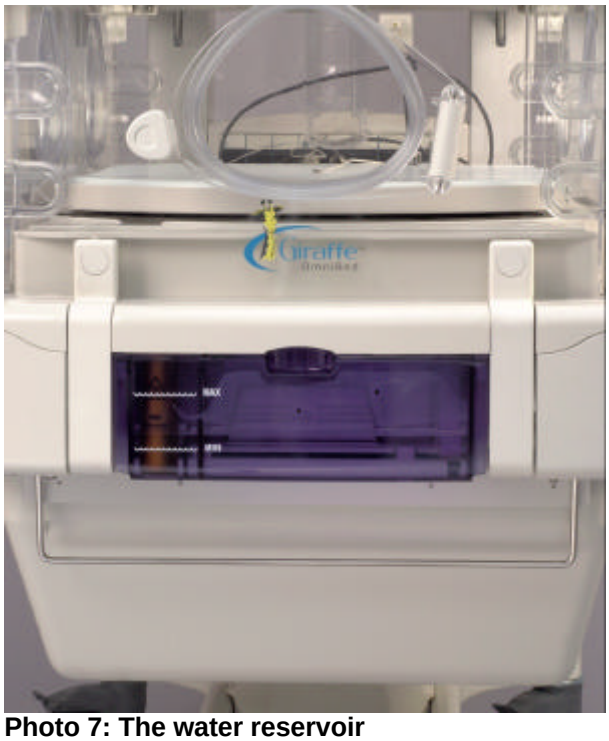


Photo 7: The water reservoir

Humidification : The Ohmeda Giraffe OmniBed has an integral humidification system option. The water reservoir is built into the end of the bassinet, furthest from the controls and contains a heater column see **Photo 7**. The heater column in the humidity system is designed to heat the water to boiling point and then release water vapour into the warm air stream conveying it into the patient chamber. The water boiling mechanism is designed to prevent infection reaching the patient from the humidity system. The water in the reservoir itself does not boil. The reservoir and heater column are marked with minimum and maximum water levels. When the reservoir is tilted open, the heater column marker corresponds to the maximum level on the plastic reservoir when it is closed.

To activate the servo-controlled relative humidity option the "three drops" icon is selected on the EL controls and information screen and the knob pressed, see **Photo 8.** The level of relative humidity can then be set in the range 30% to 95% in 5% increments by turning the knob clockwise, or deactivated by selecting "off". To confirm a choice the knob must be pressed again.

Description

Photo 8 Activating the relative humidity option

To leave the EL control and display screen EXIT must be selected by turning the knob, which should then be pressed to confirm the choice. However, it will default to the EXIT position after a short time.

Radiant Warmer Mode

The radiant heater is only activated and powered when the canopy is at its topmost position and the heater doors are fully open. The heater is a coiled metal element located behind a guard see **Photo 9**. A hemispherical reflector behind the heater is designed to focus the heat onto the mattress.

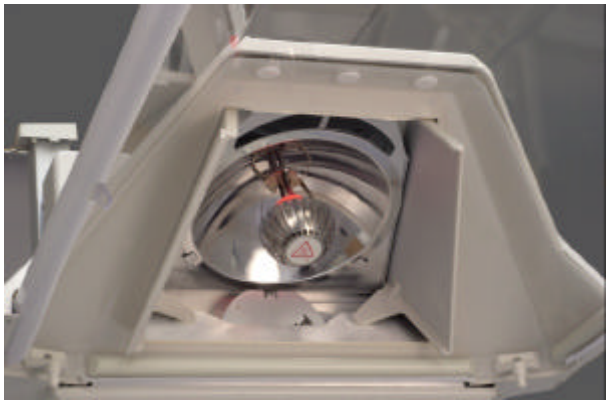


Photo 9: Radiant heater

Temperature Control : On switching into radiant warmer mode the control panel will prompt for a temperature setting. The heater can be set manually in 5% increments. If no temperature or power level is selected the Giraffe OmniBed will default into an automatic warm up mode of 100% power for 10 minutes followed by 25% power pre-warm heater setting

The factory setting of 25% pre-warm mode, up to which no alarms will be activated, can be adjusted up to 50%, using the procedure in the service manual, however, the user is warned that in doing so the device no longer complies with the safety Standard for infant radiant warmers, BS EN 60601-2-21. **CEDAR Note:** On contacting the manufacturer they confirmed that this refers to section 46.104 and "Appendix AA General Guidance and Rationale" of BS EN 60601-2-21. A radiant warmer is required to activate an alarm every 15 minutes if it is in manual mode, unless the infra-red (IR) irradiance, as measured at the mattress, is less than $10mW.cm^{-2}$. Datex-Ohmeda state that at 25% power this criteria is fulfilled. It must be noted that the heater is rated as 450W.

When a skin sensor is connected the baby's skin temperature is displayed on the temperature panel on the left of the control panel. On switching to baby control mode by pressing the baby icon a temperature between 35°C and 37.5°C can be set, in the same way as in incubator mode.

Two skin sensors may be connected simultaneously for example to measure the temperature at two sites on the baby's skin or if twin babies are co-bedded. The Giraffe OmniBed will not then operate in baby mode but will display the second skin temperature at the top right hand corner of the EL control and display panel.

Alarms: The alarm tone volume may be set at one of four levels and a bank of LEDs provides a bright visual display. All alarms usually found on an incubator or radiant warmer are present on the Giraffe OmniBed. In addition an alarm activates if the canopy is stopped in its path for more than 30 seconds while opening or closing. This is to alert the user that no heat is being generated.

Cleaning: The Giraffe dismantles down to the heater level for cleaning.

Manuals

An Operator's Manual and a Service Manual are available. Both appear quite comprehensive and the Service Manual contains useful exploded diagrams.

However, one important omission noted was that the service schedule indicated that the air filter should be changed quarterly or more frequently if used with an infectious patient, but neither the Service Manual nor the Operator's Manual explains where to find the air filter or how to change it. On closer examination of exploded diagrams in the Service Manual the air filter was found to be located behind the humidity system's water reservoir and could only be accessed when this was removed.

USER ASSESSMENT

One Senior House Officer (SHO) and 35 neonatal nurses in three hospitals and participated in our user assessment. Five Medical Technical Officers (MTOs) who had worked with the Giraffe OmniBed were also invited to comment. All three hospitals had owned at least one Giraffe OmniBed for a minimum of six months. 32 users stated that they had used the device for at least several months. Three users completed the questionnaire after using the device for the first time and only one user gave no indication of how long they had been using the device.

Our questionnaire asked users to rate features of the Giraffe OmniBed as *unacceptable, poor, satisfactory, good* or *excellent* and written comments were invited in a space beside each question. The questionnaire contained over 80 questions relating to the use of the Giraffe in both modes of operation and included general questions to ascertain the users' training and experience of the Giraffe OmniBed. Users were also asked which other incubators and radiant warmer devices they had used and then what they considered to be the advantages and disadvantages of this device. To clarify issues raised by the questionnaire an evaluator visited each neonatal unit. The numerical data response from the questionnaire is reproduced in the **Appendix** for interested readers.

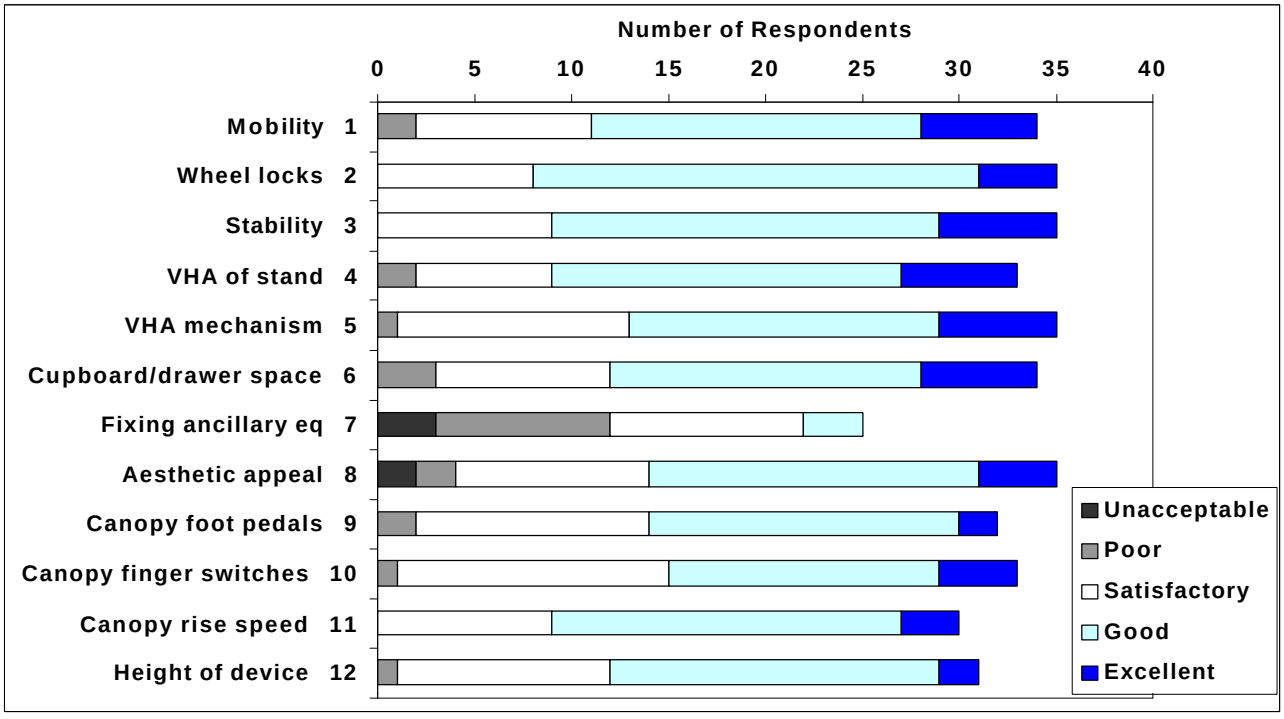
The data has been displayed graphically below to give the reader an overview of the users' response. Points of particular interest are discussed especially where users made comments about specific features.

Figure 1, below, shows the user response to questions 1 to 12, which concerned general features of the Giraffe. Most users considered the mobility, wheel locks and stability to be *satisfactory* or better, however, two nurses rated the mobility as *poor* and another commented that it was "ungainly to manoeuvre". The vertical height adjustment (VHA) was considered *good* or *excellent* by most users although some users were concerned that it was easy to confuse the two sets of foot pedals. The range of VHA was commented on favourably; the nurses found that the VHA lowered the bassinet enough for mothers seated beside the Giraffe or in a wheelchair to be able to see their child.

Some nurses found the drawer difficult to use and another noted that it could not be opened when the access doors (sides) of the bassinet were down.

Fixing ancillary equipment was also a problem, although it was only rated by 25 respondents out of a possible 36. Many were dissatisfied with the space available and some interpreted this question as relating to the availability of ancillary equipment. They were disappointed that many

Figure 1 User response, Questions 1 to 12



User Assessment

items they considered essential, for example shelves and poles, were not included in the price of the Giraffe. **CEDAR Note**: see **Manufacturer's Comments**

In a later question one user commented that battery powered syringe drivers had to be secured to the Giraffe "by tape".

The general appeal of the unit was well spread with the majority rating it as *satisfactory* or *good* but a few users rated it as *unacceptable* or *poor*.

The foot pedals for raising the canopy were generally rated well although in all three units they were disabled, either permanently or using the user settings menu. The main reason was that accidents had occurred where the canopy had been raised and had collided with other equipment attached to the wall, damaging both. One Giraffe had a cracked canopy as a result of such an accident. Nurses were also concerned that small children could step on the pedal. Disabling the foot pedals reduced the risk of their inadvertent activation. **CEDAR Note**: Once the pedal has been pressed the canopy rises in one uninterrupted movement, the pedal does not have to be held down in the same way as the VHA pedals (see **Description**).

More users scored the canopy finger switches as excellent but one user commented that they were small and "difficult to access if lots of equipment around".

The speed at which the canopy rose was well liked and considered good for accessing the baby in an emergency. The height of the device (maximum 2.36m) was not a problem for most users and one nurse noted that it was high and "out of head hitting height".

Figure 2, shows the response to questions 13 to 25 concerning the temperature controls and the ease of use.

The temperature controls were considered *good* by most users, some of whom commented that they found them easier to use when they were more familiar with them. However, some considered the controls hard to reach because they were behind the canopy.

Most users were at least *satisfied* with the temperature displays both in incubator mode and

Figure 2 User Response, Questions 13 to 25

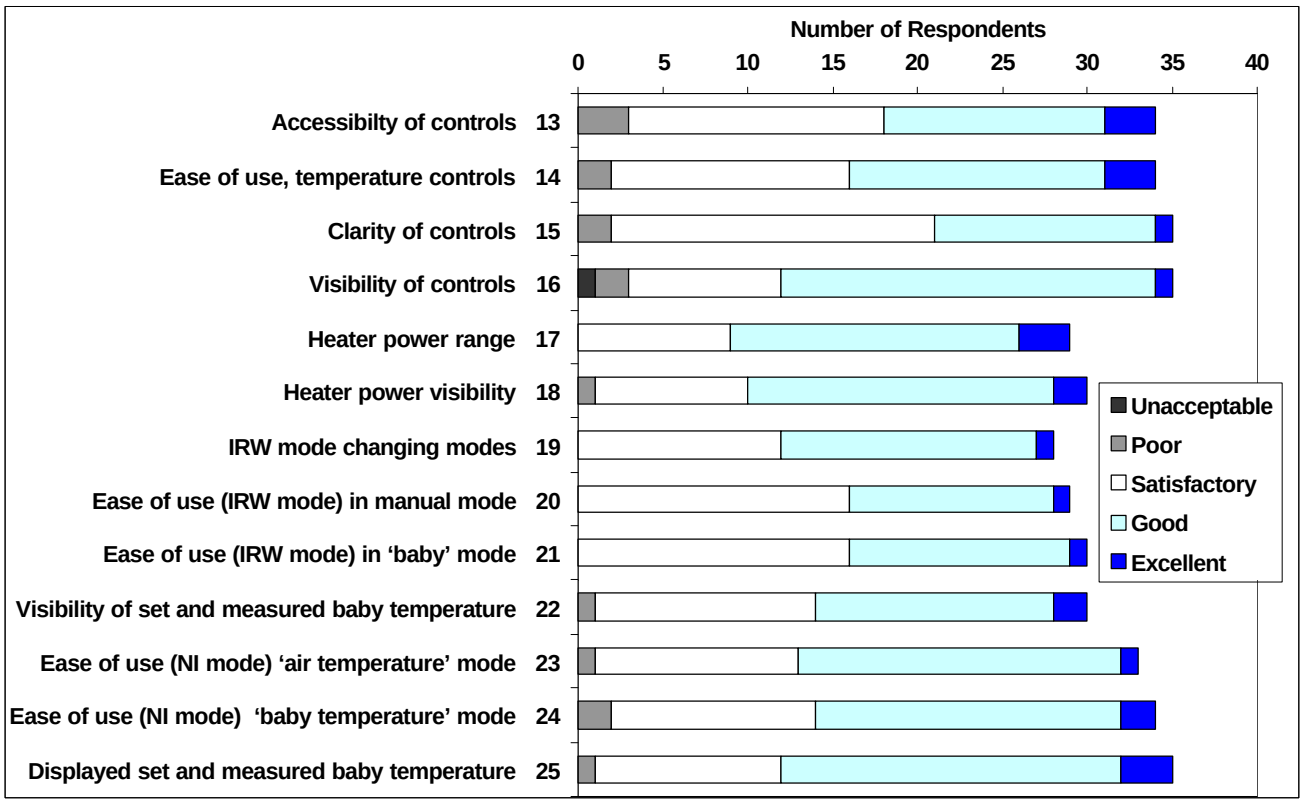
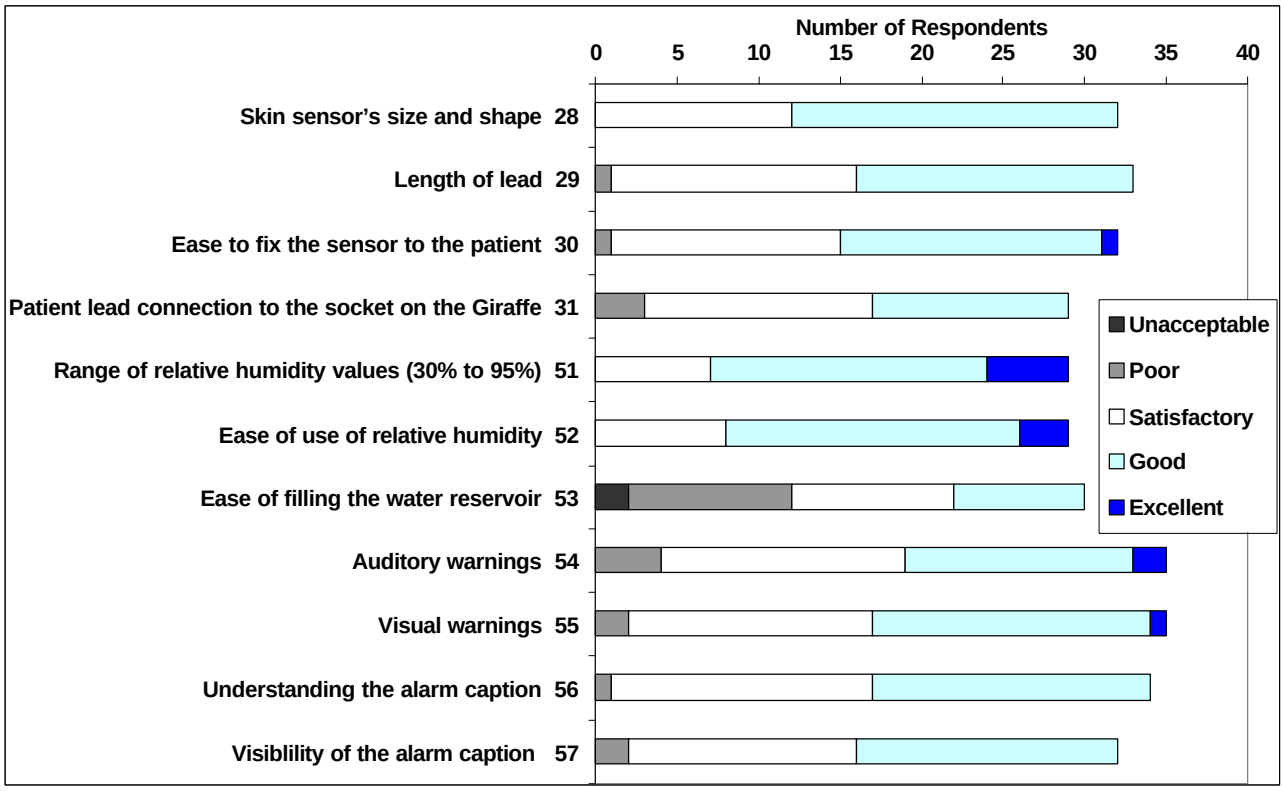


Figure 3 User Response, Questions 28 to 31 and 51 to 57



radiant warmer mode. The *unacceptable* response was accompanied by a comment that it was difficult to see the display when the patient needed phototherapy. One of the users who rated the display as *poor* commented that they could be "larger/brighter".

Figure 3 considers the skin sensor, the relative humidity system and the alarms. Both reusable and disposable skin sensors were used. Users indicated that they thought they were *satisfactory* or *good* - but neither type elicited a specific comment. The lead was thought to be a little too long and the sensor head a little large for very small babies. More nurses commented that connecting the lead to the Giraffe socket was awkward. The relative humidity feature was well liked by all the users, some thought that this was the best feature. It was considered easy to use but many nurses commented that it was not easy to open the water reservoir to refill it. One user reported that there had been "some hot water spills". A technician commented that one of the water reservoirs on their Giraffes was cracked, possibly due to the force applied to remove it.

One consultant who saw the Giraffe OmniBed but had not used it commented that he was concerned that the heater within the water would warm all of the water in the water reservoir increasing the likelihood of bacterial growth. See **Manufacturer's Comments.**

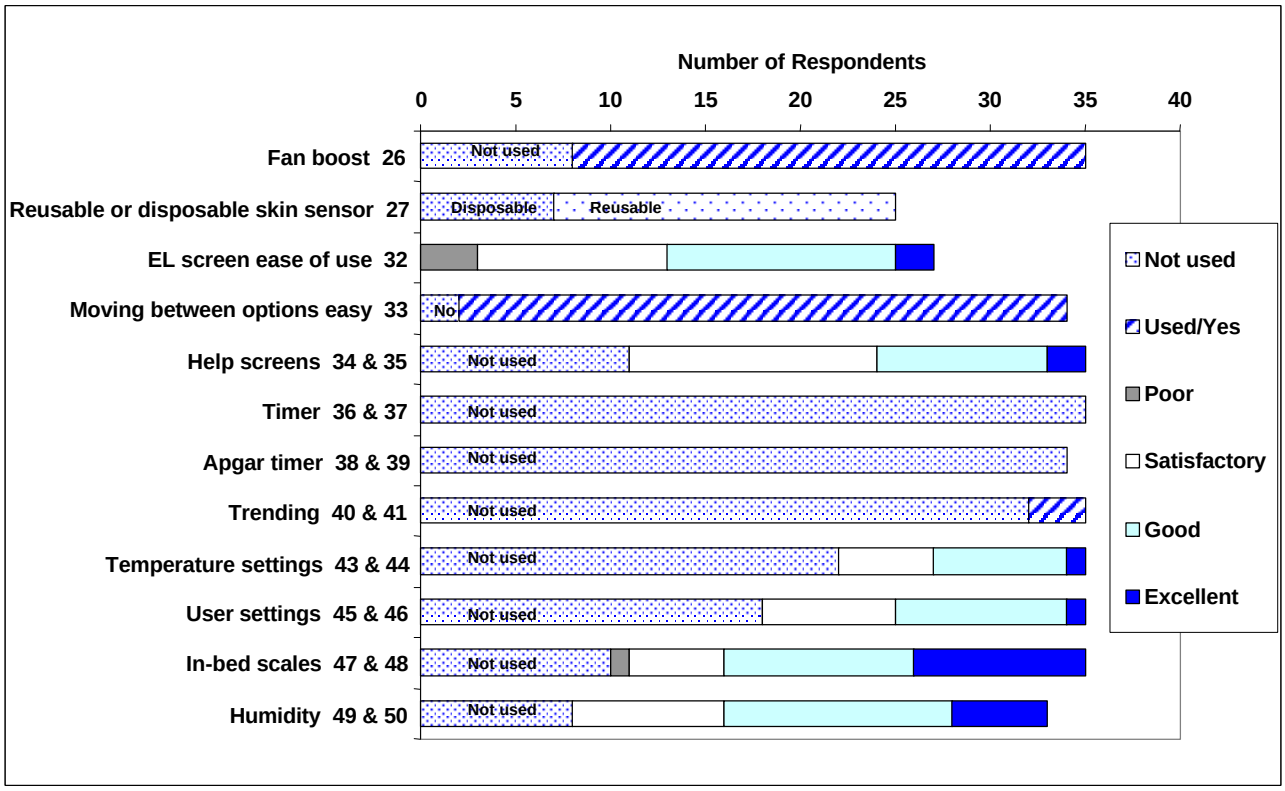
The response to the auditory and visual warnings were split very similarly with the majority of users rating these as *satisfactory* or *good*. Those who rated the auditory alarms as *poor* found it too noisy, but stated that they later found that the volume could be turned down. The visual captions on the alarm conditions were thought to be a little small.

Figure 4 is a little different from the other charts. Here, in addition to displaying the user ratings for these features we also indicate whether the respondents have used a feature of the Giraffe or not. Those who had used a feature were asked, in the next question, to rate it. The ratings are shown in the section along the bar after the block indicating those who hadn't used it.

The fan boost was a feature, that many nurses had not used. One technical comment received queried why the fan boost was not automatic on closing the incubator canopy in the transition from radiant warmer mode to incubator mode. It was very easy to forget to switch the fan boost on to enhance the speed at which the incubator attained the set temperature.

User Assessment

Figure 4 User response, Question 26, 27, 32 to 50



A few users rated the Electroluminescent (EL) screen *poor*, but most said that they found it easy to use. The help screens were found to be helpful especially when the nurses were new to using the Giraffe. None of the nurses used the Apgar timer, this feature is more appropriate for delivery suite. Neither did they use the other timing facility. Only three nurses used the trending facility and they all considered it *satisfactory* or *good*, one commented that they liked the trending facility but found that they were liable to lose the trend information between shifts when other users used the Giraffe. The in-bed scales were well liked and a high proportion of users rated them as *excellent* but two users commented that they had obtained three different readings when taking measurements consecutively. It was not clear whether this was user unfamiliarity or a problem with the scales. Care must be taken to follow the weighing procedure prompted by the EL display screen. All the users who had used the humidity facility rated it *satisfactory* or better.

None of the features considered in **Figure 4** were rated as *unacceptable*.

Figure 5 shows the responses to questions about the patient area, the mattress and the tubing ports. Again, generally these features were well liked. The mattress area was large and this was considered *good* by many nurses, although some felt that the baby looked very small in the middle. The mattress tilt was considered *good* and two users commented that they would like more tilt since some babies require it. The tubing ports were a problem for some nurses. They complained that the grommets that fitted in the tubing port holes fell off after a while and also that they clasped ventilator tubing too tightly. They preferred to use "iris" ports to route and support ventilator tubing but these were not available on their Giraffes

The use of tubing ports was also a problem in one unit where they administered oxygen directly into the canopy to provide a higher ambient level. No oxygen port was available on their Giraffes so they had to use one of the port-holes.

Mattress rotation was well liked and one user thought that this was the best feature. However, another nurse stated that mattress rotation was "easy when the bed empty. V difficult with wires, drips, ventilator tubing etc." [attached to the baby].

Figure 5 User Response, Questions 58 to 68

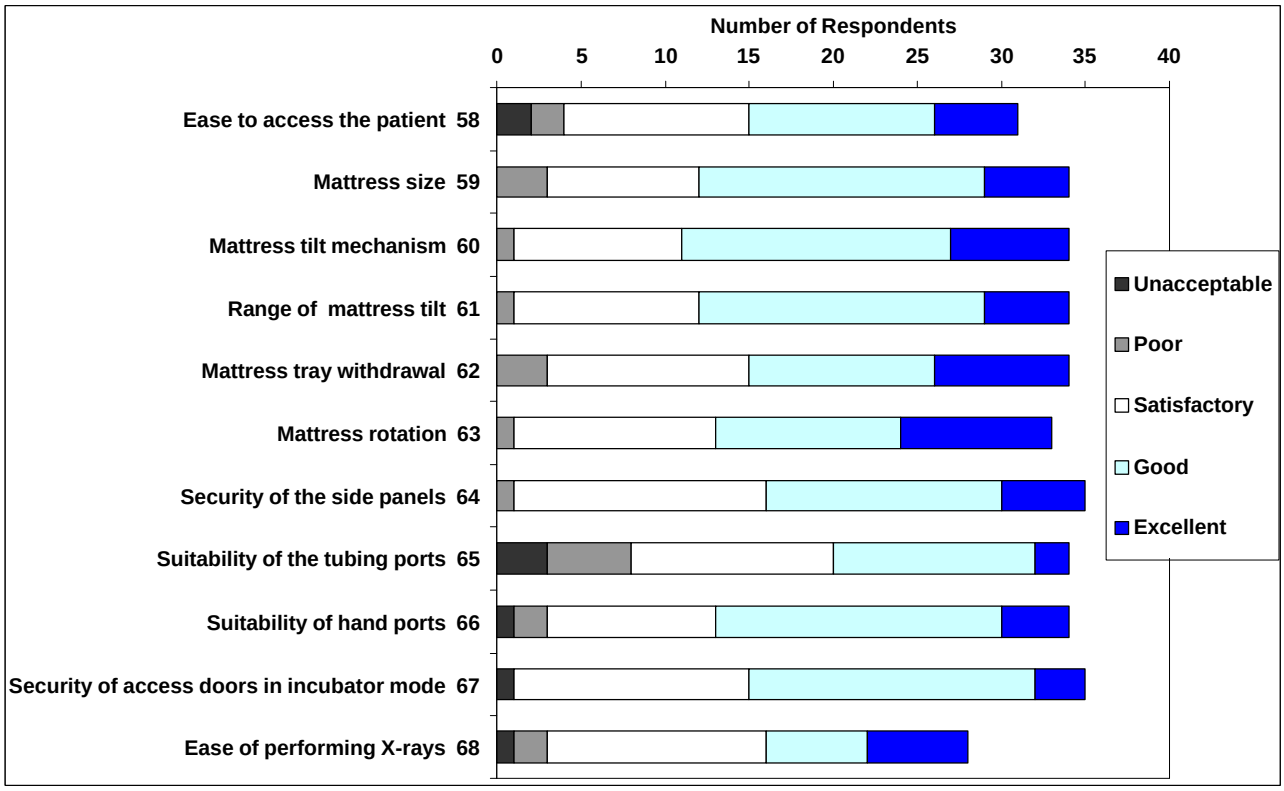
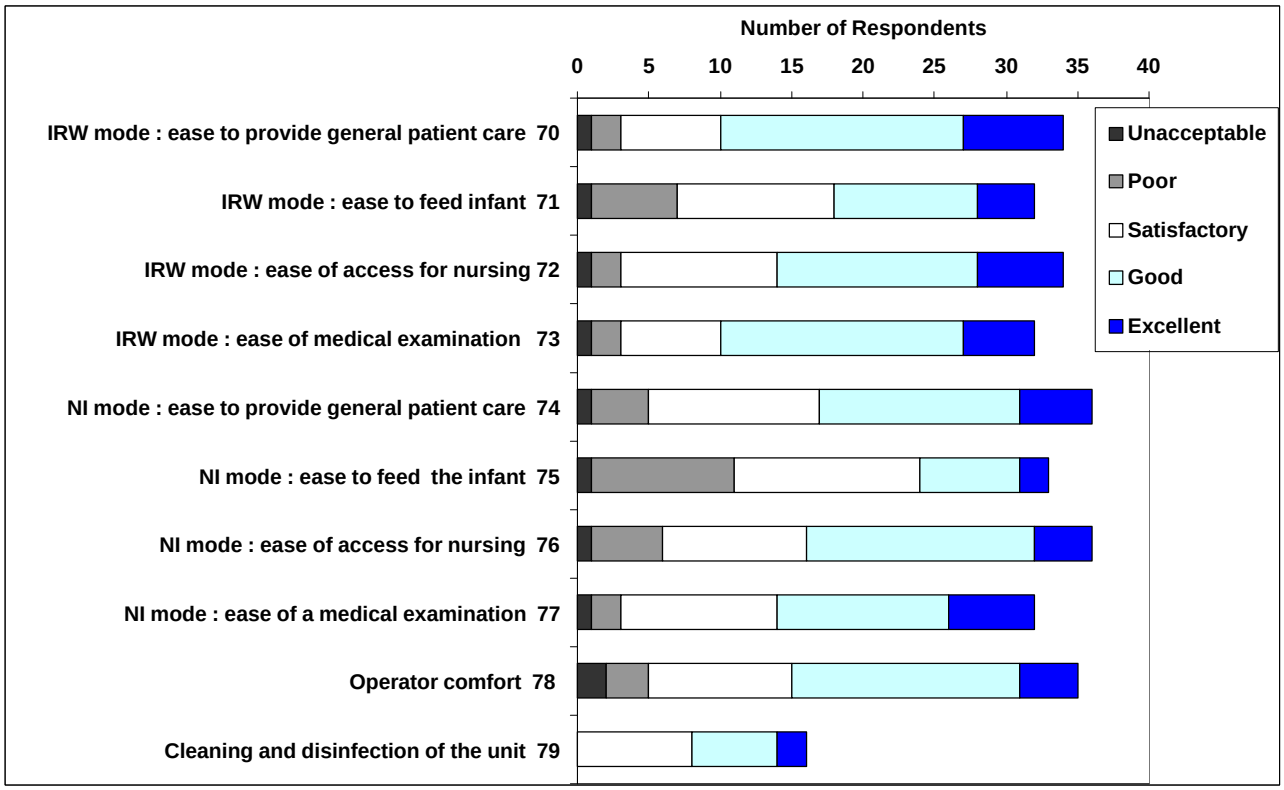


Figure 6 User Response, Questions 70 to 79


Number of Respondents
0
5
10
15
20
25
30
35
40
IRW mode : ease to provide general patient care 70
IRW mode : ease to feed infant 71
IRW mode : ease of access for nursing 72
IRW mode : ease of medical examination 73
NI mode : ease to provide general patient care 74
NI mode : ease to feed the infant 75
NI mode : ease of access for nursing 76
NI mode : ease of a medical examination 77
Operator comfort 78
Cleaning and disinfection of the unit 79
Unacceptable
Poor
Satisfactory
Good
Excellent

User Assessment

X-rays were taken by radiographers and most of the nurses thought that it was fairly easy to do.

Two neonatal units were not using the X-ray tray. At one of these a nurse stated that "due to the increased radiation required we are not using the X-ray tray". **CEDAR Note**: Local measurements of radiation dose when using the tray had led radiation protection professionals at that hospital to advise radiographers against its use. When the tray is not used babies requiring X-rays are lifted and the X-ray film placed underneath them.

Figure 6 shows the response to the questions concerning nursing and medical procedures carried out whilst the infant is in the Giraffe. One nurse rated all of the questions here as *unacceptable*, because difficulty was encountered during procedures. The Giraffe was considered wide and this made it difficult for a nurse assisting from the other side of the mattress, during a procedure. Many nurses stated that it was difficult to feed the baby using a gravity feed system since this is normally administered via a tube which is fed through a hole in the canopy of the incubator. The Giraffe OmniBed does not have a hole in the canopy. **CEDAR Note:** The Giraffe Incubator, as opposed to the Giraffe OmniBed, does have a hole in the canopy.

It was also noted that changing linens was difficult. One other problem highlighted was that during care, for example changing a nappy, it was not possible to put items safely on the canopy because it sloped.

Cleaning the Giraffe OmniBed was rated as *satisfactory* or better by most nurses although one nurse commented that it took a long time and was fiddly.

Overall the Giraffe was a well liked device. Users had become aware that special precautions were needed such as positioning it away from the wall where the rising canopy could cause an accident. Many users commented that the humidity function, the rotating mattress and the fact that it could function as both an incubator and a radiant warmer were advantages. Considering the user responses of the separate neonatal units, one neonatal unit scored the Giraffe lower than the other two. This was linked to the location of the Giraffe within their unit and an increased need for training.

The use of existing phototherapy equipment with the Giraffe led to many adverse comments. A new Ohmeda phototherapy unit designed for use with the Giraffe is not yet available in the UK. Existing stand based phototherapy units were found to be difficult to position because of the sloping canopy and aligning the stands' legs beneath the Giraffe. There is also a danger of raising the canopy whilst the phototherapy was in place.

The control panel mounted between the two rails also blocked the users' view and made it difficult for them to access devices placed on shelves behind the Giraffe.

Several users also commented on the cost of the Giraffe. They considered it expensive and were not happy that the price did not include shelves and poles that they considered an essential part of the device.

The nurses would also have liked the Giraffe to have an examination light. Indeed, in one unit the nurses found it necessary to transfer the baby to a radiant warmer with an examination light in order to insert drips and cannula. **CEDAR Note**: Examination lamps are now available.

All users, except the SHO stated that they had been trained by the manufacturer, read the manual or been trained by their colleagues.

In discussion with the MTOs working with the Giraffe they considered it to be a "well behaved" device and they had had few call outs. Only a few problems had been encountered and the support and response from Ohmeda had been good. In one unit a backup battery and transformer had been replaced, in another the mattresses had all split down the seams and had had to be replaced. The third neonatal unit encountered problems with the transformer but the Giraffe was still under warranty and Ohmeda responded the same day.

Two technicians experienced in working with incubators and radiant warmers commented that they would have liked to have been able to purchase the Service Manual from Ohmeda without attending the specific Giraffe technical training course. They also noted that when authorising purchases of expensive medical equipment allowing a budget for technical training of in-house staff expected to cover first line maintenance should be a priority.

TECHNICAL ASSESSMENT

The Ohmeda Giraffe OmniBed is a very new type of device. Ohmeda claims compliance with the general medical devices international standard BS EN 60601-1 and the standards for both neonatal incubators BS EN 60601-2-19 and infant radiant warmers BS EN 60601-2-20. Our technical assessment is based on these standards and performance tests developed at **CEDAR** in consultation with experienced clinical users of radiant warmers and incubators. Results of these tests may be compared with those of other recent evaluations of infant radiant warmers.

INCUBATOR MODE

Warm up time: We tested the speed at which the Giraffe OmniBed warmed up to temperatures commonly required for nursing sick neonates. An air control temperature of 34°C and relative humidity (RH) of 50% were chosen to simulate the conditions often used for a medium pre-term baby (~34 weeks old). Air control temperature of 38°C and maximum RH, in this case 95%, settings were chosen to simulate the conditions often used for a very pre-term baby (~24 weeks old) in their first week.

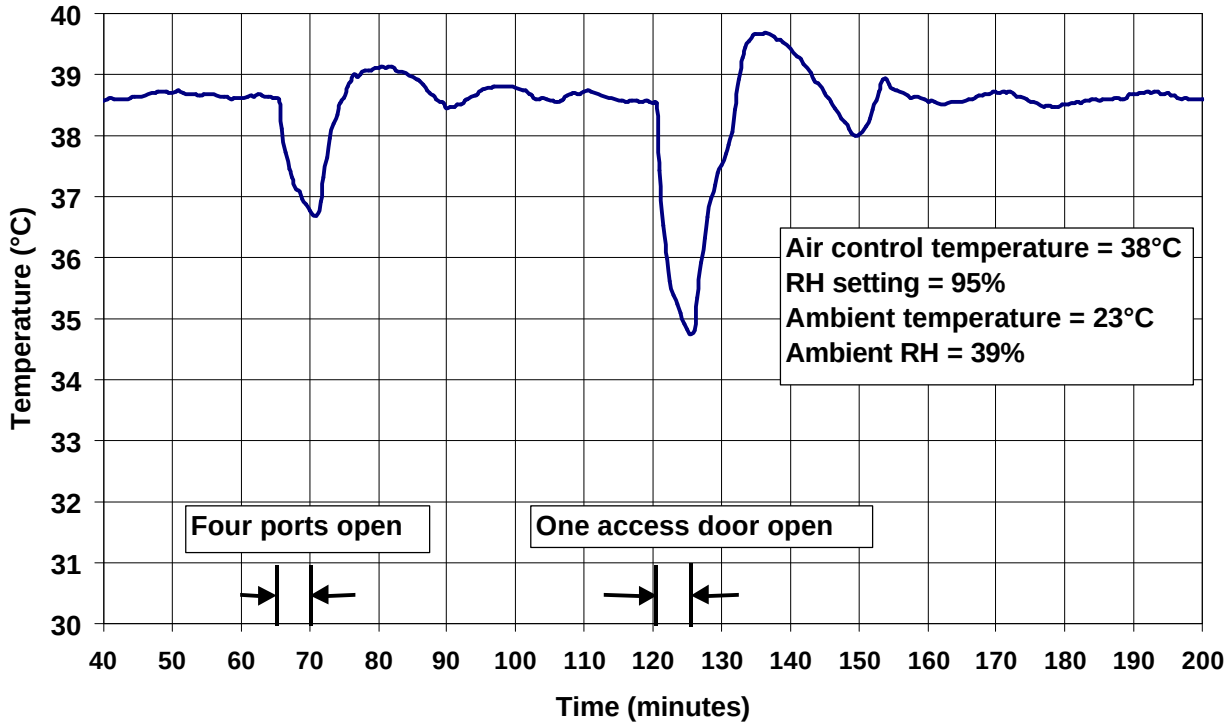
The Giraffe OmniBed warmed up from ambient room temperature to both settings smoothly with little overshoot. The times taken to achieve the temperature set are shown in **Table 1, section (a).**

Temperature Uniformity: Uniform warming in the baby compartment is very important because the neonate needs a stable isothermal environment in which to thrive. Trying to maintain his/her temperature reduces the energy a neonate has available for growth and maturity.

The temperature across the mattress was measured at 10cm above the mattress as described in the harmonised standard BS EN 60601-2-19 for incubators. The variation of temperature across the mattress while horizontal and while in its extreme tilted positions of 12° towards or away from the control panel are shown in **Table 1 section (b)**. To access the tilt mechanism an access door or a port must be opened briefly, this results in a small temperature drop of approximately 1.3°C.

Opening ports or access doors to gain access to the neonate for medical or nursing procedures lowers the incubator temperature. To assess this temperature drop the Giraffe OmniBed was set at 38°C in air temperature control mode and maximum RH, 95%. When a steady state had been achieved four hand ports were opened for five minutes. After the ports had been closed and a steady temperature state was re-established one of the two access doors was opened for five minutes. Opening the four ports causes the temperature to drop by 1.9°C, it quickly recovers but an overshoot of 0.5°C was observed, see **Figure 7,** and **Table 1 section (c).**

Figure 7 Effect of opening hand ports and access door on air temperature



Technical Assessment

Table 1

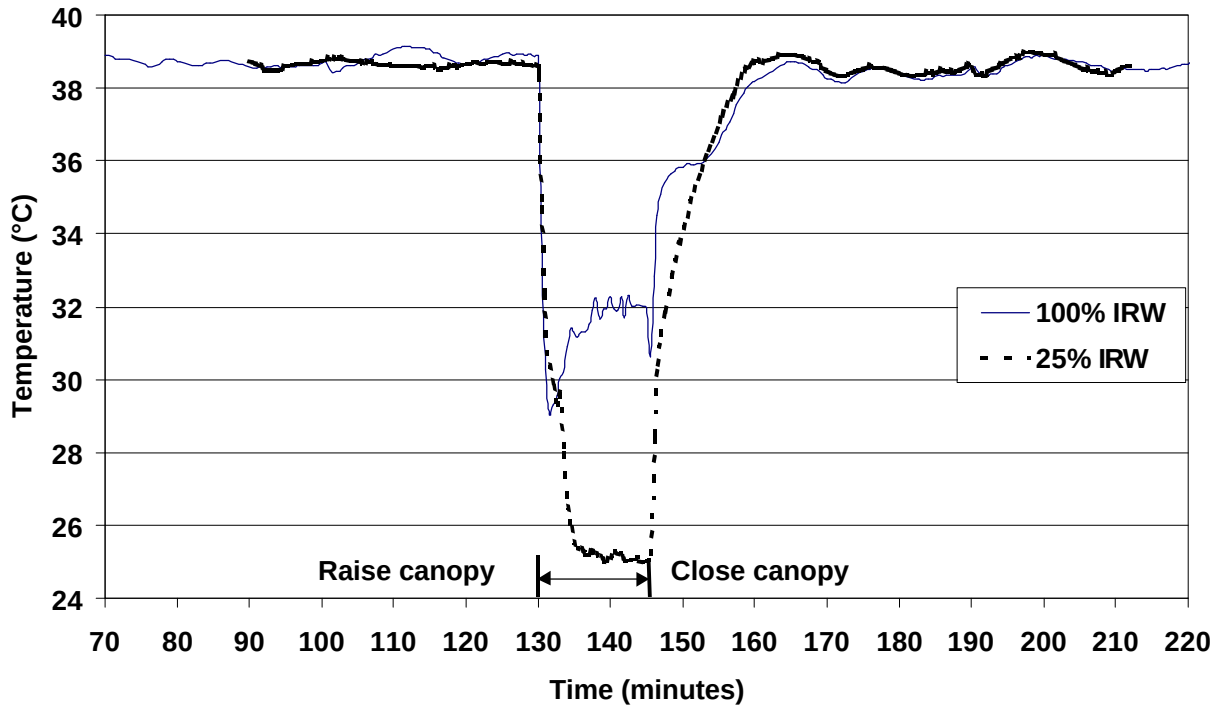
Neonatal Incubator Mode	
Section (a) Warm up time using	
Air control temperature set to 34°C and RH set to 50%	32.5 minutes
Air control temperature set to 38°C and RH set at 95% (max value)	50 minutes
Section (b) Temperature Uniformity (air control temperature of 38°C and RH 95%)	
Mattress horizontal	± 0.3°C
Mattress tilted towards controls	± 0.1°C
Mattress tilted away from controls.	± 0.4°C
Section (c) Opening ports and doors (air control temperature of 38°C and RH 95%)	
Time to regain 38°C after opening 4 ports for 5 minutes	3 minutes
Temperature overshoot above previous average temperture	0.5°C
Time to regain 38°C after opening one access door for 5 minutes	6 minutes
Temperature overshoot above previous average temperature	1.1°C

Opening the access door caused a larger temperature drop of 3.6°C but the set air temperature, 38°C, was regained in only 6 minutes. However, once again, there was a temperature overshoot of 1.1°C after the door has been closed, as shown in **Figure 7** and **Table 1 section (c).** This result can be compared to the response of other incubators to this test shown in the earlier evaluation report ***Evaluation* 375**; the overshoot is well within the limits set by the standard, ± 2°C.

Relative Humidity: Measurements of RH were made during the above tests. When the access door or four ports were opened for 5 minutes the RH dropped from its set value of 95% to around ambient RH, in this case 50%. The set RH level was quickly regained in 2 minutes once the door or ports were closed again, performing as well as other incubators evaluated in ***Evaluation* 375**.

Transition from Incubator Mode to Radiant Warmer Mode, Raising the canopy:
The Giraffe OmniBed is designed to provide good emergency access to a sick neonate being nursed in an incubator by changing swiftly from incubator mode to radiant warmer mode. Its ability to maintain a steady thermal environment for the

Figure 8 Effect of raising the canopy and setting the radiant heater at 25% and 100% power.



baby is also important. To simulate the impact on a neonate of the change from incubator mode to radiant warmer mode we monitored the change in temperature 10cm above the mattress using the same experimental set-up as for testing the Giraffe in incubator mode.

The Giraffe was stabilised at 38°C, air control temperature and 95% RH (maximum level). The canopy was then raised and the radiant heater set to its default value of 25%. After 15 minutes the canopy was lowered and the Giraffe OmniBed reset to the original settings, the high fan speed option was activated once the canopy had been lowered to allow the Giraffe OmniBed its optimum warm up rate. The temperature dropped by 13.6°C to 25°C, a little above the ambient temperature of 22.9°C, as can be seen in **Figure 8**. On closing the canopy the air control temperature, 38°C, was regained in 12.5 minutes.

The Giraffe temperature was re-stabilised in air controlled incubator mode and the procedure above repeated using 100% radiant warmer power whilst the canopy was raised, see **Figure 8**. This time the temperature dropped initially by 9.8°C but then rose to settle around 32°C. On closing the canopy the temperature dipped again briefly to 30.6° before rising to regain the set temperature of 38°C in 14 minutes. Recovery time was prolonged by a "saddle point" at 36°C. It appeared that the Giraffe tried to use 36°C as the set temperature before continuing to warm up to 38°C. No change on the display was noticed.

For ease of comparison only the temperature of the central thermometer is shown and graphs of the two tests have been superimposed in **Figure 8**. In both procedures the boost air curtain option was activated after closing the canopy to enable optimum re-warming of the incubator. **CEDAR note:** It is easy to forget to manually activate the auxiliary fan, which is not automatic on closure of the canopy.

Table 2

Transition	
Time to regain 38°C in incubator mode after 25% heater power.	12.5 minutes
Time to regain 38°C in incubator mode after 100% heater power.	14 minutes
Time to regain 36.5°C in radiant warmer mode after lowering the canopy and switching off	8.5 minutes

Using 25% heater power provides very little heating effect to the mattress and the temperature drops to just 2°C above ambient room temperature. 100% radiant heater power on raising the canopy can be seen to have an appreciable effect, the temperature drops and then stabilises at 32°C. When the canopy is closed the temperature drops again briefly before rising to regain the set temperature of 38°C. This demonstrates that if the canopy is raised then setting the heater at 100% power provides a warmer environment than using the pre-warm value of 25% heater power.

At the lower heater power the Giraffe takes a shorter time to regain 38°C. On closing the canopy after using 100% heater power the Giraffe OmniBed appears to try to reach a temperature of 36°C as the shallow "saddle point" on the graph shows, before moving up to 38°C. These results are shown in **Table 2**. The average time to raise and lower the canopy is discussed later in this **Technical Assessment**.

For a comparison of the temperature fall measured during opening the incubator canopy, opening four port holes and opening the access door see **Table 3.** As expected, opening the port holes results in the smallest temperature disturbance to the baby, whilst raising the canopy produces the largest.

Table 3

Test - with the Giraffe set at 38°C and 95% RH	**Temperature drop**
Open 4 ports for 5 minutes	1.9°C
Open 1 access door for 5 minutes	3.6°C
Raise the canopy for 15 minutes, use 25% power	13.6°C
Raise the canopy for 15 minutes use 100% radiant heater power.	9.8°C

Technical Assessment

RADIANT WARMER MODE

Temperature was measured using five matt black aluminium discs constructed and positioned on the mattress as described in BS EN 60601-2-21 the standard for infant radiant warmers.

Warm up time: Using the Giraffe's automatic pre-warm mode, 100% power for 10 minutes then 25% heater power, raised the temperature of the central disc on the mattress by 4.7°C after 30 minutes, as shown in **Table 4.** The temperature continued to rise slowly at a rate of 0.5°C per hour over and above the ambient temperature.

Table 4

Radiant Warmer Mode	
(a) Temperature rise using Manufacturer's pre-warm after 30 minutes	4.7°C
Maximum heat after 15 minutes	5.9°C
(b) Time to warm disc to 36.5°C Max heat from ambient (23°C)	38 mins
Max heat from pre-warm temp (28.3°C)	24 mins
Temperature variation when horizontal at 36.5 baby temperature	1.3°C
Temperature variation when tilted towards controls	0.6°C
Temperature variation when tilted away from controls	2.2°C

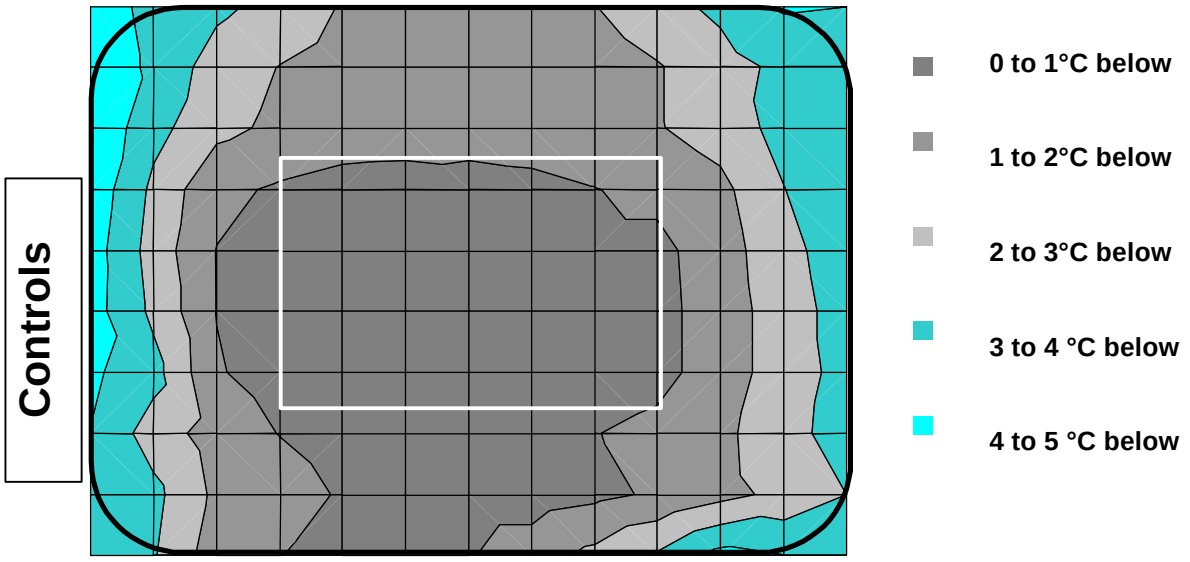
The time to achieve 36.5°C skin control temperature from the pre-warm state and from ambient cold start were also measured as it was considered that these would be conditions under which the Giraffe OmniBed may be used.

Temperature Stability: From a steady state the variation in temperature across the mattress, when horizontal, and when in each of its two extreme tilted positions were measured, and are shown in **Table 4.** In the horizontal position the temperature variation should be less than 2°C to comply with the standard. There are no specification for when the mattress is tilted but as shown in **Table 4** a 2.2°C variation was measured when the mattress was tilted away from the controls.

Simulation of an internal transfer: To assess the performance of the Giraffe OmniBed when used in radiant warmer mode but needed for an internal transfer between departments in a hospital the following test was devised.

The Giraffe OmniBed was set in skin control mode at 36.5°C and stabilised. The canopy was then closed and the Giraffe OmniBed prompted the user for a temperature setting for incubator mode. The device was then switched off for 15 minutes to simulate its condition during an internal transfer, since it has no backup battery to maintain power during a power failure. When switched on again the canopy was raised to its full extent, the

Figure 10 Surface temperature of the mattress at 50% radiant heater power (max temperature = 34°C)



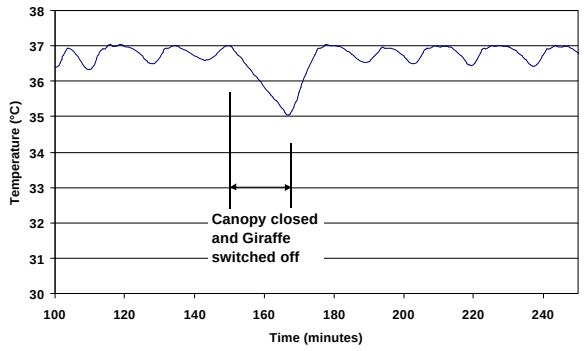


Figure 9. Simulation of an internal transfer - the effect on temperature

Giraffe automatically entered skin control mode and the 36.5°C temperature setting was confirmed. Changes in temperature during this test are shown in **Figure 9**. The temperature dropped by 1.8°C and recovered to an average temperature of 36.8°C, while set at 36.5°C, in 8.5 minutes. It must be noted that this figure shows how the temperature as measured within the disc fluctuated between 36.5°C and 37°C. The periodicity was approximately 17 minutes. **CEDAR Note**: There are no specific limits on fluctuations of temperature. This data is provided for comparison with other ***Evaluation*** reports.

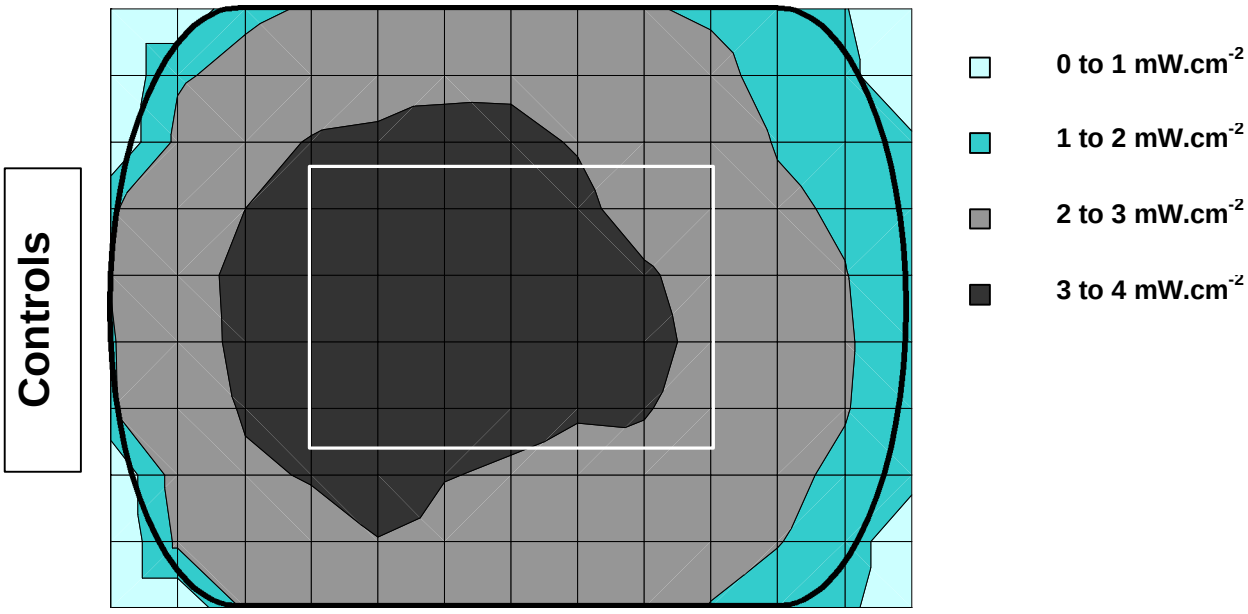
Surface Temperature: The uniformity of heating across the mattress is important to clinical users of radiant warmers. To assess this the Giraffe OmniBed was set at 50% manual power output and the mattress was covered with a black felt sheet marked at 5cm intervals. After one hour a surface temperature probe was used to measure the temperature at each of the marked points. The contours in **Figure 10** display the temperature difference from the maximum, 34°C, at the centre of the mattress. It is seen to be slightly skewed to the left and the contours are tighter towards the controls end of the mattress, which could be attributed to the shape of the reflector behind the radiant heater element directing the heat onto the oval shaped mattress. The black oval shape on **Figure 10** represents the approximate dimensions of the mattress.

The temperature variation in the central area of the mattress, 20cm by 30cm, as shown by the white box, is mostly within 1°C of the maximum temperature. This is a good result as it shows that the centre of the mattress provides a uniform thermal environment, but it also shows how important it is to place the baby in the centre of the mattress to reduce thermal stress.

The skin temperature sensor was placed at the centre of the mattress during the measurements and covered with a reflecting pad, as it would be when used on a baby. The temperature of the skin sensor displayed on the Giraffe OmniBed control panel agreed with the temperatures measured at the centre of the mattress**.**

Irradiance Contour Mapping: The temperature measured is dependent on the time the radiant heater has been operating. Measurement of the

Figure 11 IR irradiance at 50% radiant heater power



infrared (IR) irradiance produced provides a more objective assessment of the effectiveness of the radiant heater, because it is not affected by air flow variations across the mattress. The IR irradiance on the mattress was measured at the same positions as the previous set of temperature measurements using an IL1400A radiometer calibrated for 780nm, **Figure 11**.

This plot of irradiance in the IR region clearly demonstrates the focus of the radiant heater reflector. It can be seen that the warmest part of the mattress extends from the centre towards the control panel. The areas around the edge showing a zero value of irradiance are positions outside the edge of the mattress where the irradiance was not measured. These have a default value of zero. The maximum irradiance measured at 50% power was 3.2mW.cm^{-2}. At 100% power the maximum irradiance measured was 13.45mW.cm^{-2}. Irradiance in the central region was greater than the 10mW.cm^{-2} maximum limit in the radiant warmer standard, BS EN 60601-1-21, and covered over 50% of the mattress area. Irradiance levels greater than this limit are permissible for short periods as no harmful incidents had been reported at the time of the standards publication. **CEDAR Note:** These levels of irradiance may be compared to recent measurements on other infant radiant warmers ***Evaluations* 01043 *and* 01044**.

Humidification system: The heater in the water reservoir heats the water to boiling point and the water vapour is released into the warm air stream. The water heater, however, is immersed in the reservoir and warms all of the water. The temperature of the outside of the reservoir and above the reservoir varies from 33°C to 53°C indicating that all of the water in the reservoir becomes hot. The surfaces around the reservoir become warm but their temperature does not exceed the limits set by the standard BS EN 60601-1 for excessive temperatures.

Measurements of the relative humidity showed agreement within the limits set by the standard, ±10% of the indicated relative humidity value at values below 70%. Above 70% the discrepancy between the displayed relative humidity level and the measured level exceeded 20%.

Sound levels: The noise level within the baby compartment was measured during normal operation as an incubator, with the alarm sounding at its four noise levels and whilst raising the canopy see **Table 5**. The noise level during normal operation is below the 60dB(A) limit set by the standard. Neither the alarm levels nor raising the canopy are considered to be part of "normal operation" and so these levels may exceed the 60dB(A) limit. The alarm noise level limit is 80dB(A) and even at Level 4 the Giraffe alarms are well below this. The decibel A (dB(A)) scale is weighted to correspond to the response of the human ear. Although the general noise level measured here is low the general overall neonatal noise exposure must be kept to a minimum.

Table 5 Sound levels on the mattress

	Noise level
Incubator mode	55 dB(A) ±2dB(A)
Raising the canopy	68 dB(A) ±2dB(A)
Alarms (level 1 to 4)	48 to 66 dB(A) ±2dB(A)

Canopy Travel: The time taken to raise and lower the canopy was measured because it would influence the clinical use of the Giraffe OmniBed. The canopy ascended quickly once it was activated, and rose to the top of its travel in approximately six seconds. It could be stopped in its ascent by pressing the finger switch or foot-switch again. Descending the canopy was slower, and took approximately 14 seconds, however, if an object, for example a hand, was in the path of the descending canopy, the canopy would not stop and pressure would be applied to the object. A safeguard built into the design was that the canopy could only be lowered by pressing and holding the down finger switch. Once released the downward travel would stop.

Height: The height of the device in its various configurations is given in the **Manufacturer's Data** section. As the maximum height of the overhead heater exceeds two meters, care must be taken to ensure that there is enough headroom to raise the canopy of the Giraffe OmniBed to radiant warmer mode.

CERTIFICATION AND STANDARDS

Medical devices placed on the market in the European Union are required to comply with the relevant European Union Medical Devices Directive. Manufacturers must display the CE mark on the device as a declaration that it meets the appropriate provisions of the relevant legislation including those relating to safety and where required has been assessed in accordance with these.

The Giraffe OmniBed carries CE marking in respect of the Medical Devices Directive (MDD). Datex-Ohmeda submitted a certificate confirming compliance with European Council Directive 93/42/EEC, based on full quality assurance, Annex II of MDD. The Notified Body was BSI, UK, (0086), device classification IIb. Datex-Ohmeda also supplied a certificate from Ohmeda Medical, Laurel, MD USA stating that the Giraffe OmniBed System is a Class 1 device with Type B applied parts and that it had been type tested by Canadian Standards Authority (CSA) International. They had issued a CB Test Certificate stating that it was found to be in conformity with: International Electrotechnical Commission (IEC) 60601-1 (the general safety standard) edition 2:1988, including amendments 1 (1991) and 2 (1995), IEC 601-2-19 (particular standard for incubators) and IEC 601-2-21 (particular standard for radiant warmers).

Procurement issues: All prices in this report exclude VAT, and are correct at time of going to print, however, you are encouraged to contact Datex-Ohmeda at the address given for current prices and configurations.

Training: User knowledge and skills have major implications for safety. Procurement of a new medical device should include a resource allocation for user training and also any technical training for the Clinical Engineering/EBME technical staff should they be required to maintain it.

MANUFACTURER'S COMMENTS

Generally we consider this a very favourable review of the Giraffe OmniBed, both technically and from a user assessment. We have addressed some of the points raised below.

***Water Reservoir**: A design modification to the top of the reservoir has greatly improved accessibility. This new design was incorporated into new Giraffe products from 17/6/2002. New lids will be shipped free of charge to all existing Giraffe customers during summer 2002. The temperature of the reservoir water has been measured to be 52° to 58°C, this is considered bactericidal to most mesophilic micro-organisms (that may thrive in the human body or act as pathogens).*

***Tubing Grommets** have undergone a design change to improve retention. Changed parts were provided free of charge to all customers who had purchased a Giraffe OmniBed.*

***The air circulation fan** operates at 1000 & 1500 rpm. High fan speed is activated under 4 conditions: 1) for 90 minutes after unit start up as an incubator 2) for 45 minutes after transition from warmer to incubator 3) whenever the Boost Air button is activated and 4) if the heater temperature exceeds a pre-set temperature.*

***Sloping canopy** : This and the omission of a hole are intentionally part of the design for safety reasons. It is not prudent to suspend or place equipment on a device with a rising canopy. Developmental care principles identify that placing items on top of a canopy raises sound levels within the hood and carries a risk of marking or damaging the surface of the hood, particularly where liquids are used.*

***Ancillary equipment** may be requested when purchasing the OmniBed to allow users to customise the OmniBed to their requirements. Most users do not request this level of information. Exam lights and phototherapy spot lights are available for the Giraffe, they may be ordered with connectors for wall sockets or accessory power outlets and mount on the rail system. Ventilator tubing support is also now available.*

***Sound levels** of 55 ± 2dB(A) correspond to the Giraffe OmniBed in incubator mode in Boost Air Mode. The conditions under which the Giraffe normally operates expose the patient to a noise level of 46 ± 3 dB(A)*

*The **control panel** location at the head of the device is designed to be accessible from both sides, allowing wider visibility of the information and it is also better protected from knocks.*

*The **temperature sensor connector** is deliberately placed to prevent accidental removal and damage to the sensor from frequent removal. Their interfaces are not generally required to be manipulated frequently.*

***Mattress rotation** allows improved access to the baby and it can be positioned far more appropriately.*

***Cost:** The product can be thought of as two separate devices (incubator and warmer), adding in the cost of the extra built in features (scales, trending, tilt etc) and coupled with not having to transfer the baby between devices you have a very competitively priced product.*

Manufacturer's Data

PRODUCT DATA

Manufacturer	Ohmeda Medical, 8880 Gorman Road, Laurel MD 20723, USA	
Country of Origin	United States of America	
Prices (ex VAT)	Giraffe OmniBed (standard) including elevating base, in-bed scales and servo relative humidity	£ 27,000
	Giraffe OmniBed (as above) with servo oxygen	£ 29,000
	Monitor shelf	£ 700
	Instrument shelf	£ 425
	IV mounting pole	£ 200.72
	Ventilator mounting pole	£ 234
	Utility post	£ 99.84
	IV dual hook 12"	£ 122.72
	IV pole dual hook 24"	£ 155
	Porthole wristlets (box of 8)	£ 25
	Hood cover	£ 150
	Filter (pack of 10)	£ 50
	Tubing management arm	£ 250
	Fitted mattress cover	£ 50
	High Frequency Oscillatory Ventillation (HF OV) porthole	£ 135
	Disposable patient probe (box of 10)	£ 150
	Disposable patient probe (box of 50)	£ 650
	Reusable patient probe	£ 150
	Heat reflecting patch (box of 50)	£ 13
	Examination lamp (specify Giraffe plug or wall outlet plug)	£ 850
	Phototherapy lamp (Spot light) (specify IEC or UK plug)	TBC

Physical Data

Size (H x W x D)	147cm to 236cm (with VHA and canopy raised) x 69cm x 112cm
Weight	129kg
Mattress size	65cm x 50cm
Bed tilt	±12° continuously adjustable
Heater movement	Does not rotate
Castors	4 locking
Heater power	450W

PRODUCT SUPPORT

Supplier	Datex-Ohmeda 71 Great North Road Hatfield Hertfordshire AL9 5EN	Tel : 01707 263570 Fax 01707 260065 Web : www.ohmedamedical.com
Guarantee	1 year	
Servicing	Warranty Extension with Planned Preventative Maintenance	£ 1153.17 per year
	Fully comprehensive for a 3 or 5 year period (Includes year 1 maintenance) Only available at time of sale	
	Planned Preventative Maintenance (includes routine labour and parts)	£ 960.93
	Comprehensive (includes routine labour and parts and corrective maintenance labour and parts)	£ 1537.45
	Biomed partnership with corrective maintenance (includes second level training, routine parts and corrective maintenance labour and parts)	£ 1153.17

Appendix

Table A1 User assessment data from questionnaire The number of users sharing the same opinion about a feature is recorded, eg 17 users thought general mobility was good. The most common response is marked in **BOLD**. For some features only a few users scored their opinion on their questionnaire.

Number	Question	Unacceptable	Poor	Satisfactory	Good	Excellent
	Part 1 General					
1	What is your opinion of the **general mobility** of this device?		2	9	**17**	6
2	What is your opinion of **wheel locks**?			8	**23**	4
3	What is your opinion of the **stability** of this device?			9	**20**	6
4	What is your opinion of the **vertical height adjustment** of the device?		2	7	**18**	6
5	What is your opinion of the **VHA mechanism** of the device?		1	12	**16**	6
6	What is your opinion of the **cupboard/drawer** space on the unit?		3	9	**16**	6
7	What is your opinion of the **fixing of ancillary equipment** to this device?	3	9	**10**	3	
8	What do you think about the **aesthetic appeal** of the unit?	2	2	10	**17**	4
	Part 2 Conversion from Incubator to Radiant Warmer and vice versa					
9	What is your opinion of the **foot-switches** for **raising the canopy** to radiant warmer mode?		2	12	**16**	2
10	What is your opinion of the **finger-switches** for **raising and lowering** the canopy?		1	**14**	**14**	4
11	Please indicate your opinion of the **speed of raising and lowering the canopy**			9	**18**	3
12	Please indicate your opinion of the **height** of the device when in radiant warmer mode		1	11	**17**	2
	PART 3 Temperature Controls and Sensor					
13	Please indicate your opinion of the **accessibility** of the Giraffe temperature and accessory controls		3	**15**	13	3
14	What is your opinion of the general **ease of use of all Giraffe temperature controls**		2	14	**15**	3
15	How **clear** do you find the controls?		2	**19**	13	1
16	How **visible** are the Giraffe temperature controls?	1	2	9	**22**	1
	Radiant warmer mode					
17	**What is your opinion of the range of heater control in manual mode**? (0% to 100%)			9	**17**	3
18	How do you find the **visibility** of the **heater power level**?		1	9	**18**	2
19	How easy do you find it to **change the Giraffe temperature in radiant warmer mode** between 'manual' and 'baby'?			12	**15**	1
20	**How easy do you find it to use the** radiant warmer controls in '**manual'** mode?			**16**	12	1
21	**How easy do you find it to use the** radiant warmer controls in '**baby'** mode			**16**	13	1
22	How do you find the **visibility** of the **set and measured baby temperature?**		1	13	**14**	2
	Incubator mode					
23	**How easy do you find it to use the** incubator temperature controls in '**air temperature'** mode?		1	12	**19**	1
24	**How easy do you find it to use the** incubator temperature controls in '**baby temperature'** mode?		2	12	**18**	2
25	What is your opinion of the display of the **set and measured baby temperature?**		1	11	**20**	3
26	Do you often use the **boost air curtain auxiliary** fan?	Yes = 8				
27	Please **circle** the **type of skin sensor** you use: **disposable** OR **reusable**	Disposable = 7 Reusable = 18				
28	What is your opinion of the skin sensor's **size and shape**?			12	**20**	

Appendix

Number	Question	Unacceptable	Poor	Satisfactory	Good	Excellent
29	What do you think of the **length of lead**?		1	15	**17**	
30	How easy do you find it to **fix the sensor** to the **patient** ?		1	14	**16**	1
31	What is you **opinion** of the **patient lead connection** to the socket on the Giraffe?		3	**14**	12	
	PART 4 Electroluminescent (EL) Graphic Control and Display Screen					
32	Please give your **opinion** of the **EL graphic control/display screen** on the right hand side of the control panel		3	10	**12**	2
33	Do you find it easy to use and **move between options**?	Yes = 32				
34	Have you used the "**?**" icon which accesses the **help screen** ?	Yes = 24				
35	What is your **opinion** of the **help screens** available from this menu?			**13**	9	2
36	Have you used the **timer option**, accessed by selecting the **clock icon**?	Yes = 0				
37	If so, what is your **opinion** of the **timer options**?					
38	An **Apgar timer** with tones can be activated from this menu, **have you used it**?	Yes = 0				
39	If so, what is your **opinion** of it?					
40	An information **trending screen** can be accessed by selecting the **stylised graph icon**, have you used it?	Yes = 3				
41	If you have used the trending screen please tick which trending lines have been **useful** to you					
	Patient temperature	Yes = 2				
	Air temperature	Yes = 3				
	Set temperature					
	Relative humidity	Yes = 2				
	Heater power					
42	What is your **overall opinion** of the **trending screen and information**?			1	**4**	
43	The next icon, **a smiling face and thermometer**, accesses a menu which gives information on possible temperature settings for different age and birth-weight babies. **Have you used it**?	Yes = 13				
44	If you have used it, what is your **opinion** of this **feature**?			5	**7**	1
45	The **spanner symbol** accesses the **settings menu** for changing alarm volume, patient alarm settings and other user settings. **Have you used this**?	Yes = 17				
46	If so, what is your **opinion** of the **settings menu**?			7	**9**	1
47	If your Giraffe has **in-bed scales** the **scales symbol** accesses the **in-bed scales menu. Have you used this**?	Yes = 25				
48	If so, what is your **opinion** of this **feature**?		1	5	**10**	9
49	The **three drops** icon accesses the integral **relative humidity** control and display menu. **Have you used this feature**?	Yes = 25				
50	If so what is you **opinion** of this **feature**?			8	**12**	5
	PART 5 Relative Humidity					
51	What is your opinion of the **range of relative humidity values** (30% to 95%)?			7	**17**	5
52	What is your **opinion** of its **ease of use**?			8	**18**	3
53	What is your **opinion** of the **ease of filling the water reservoir**?	2	**10**	**10**	8	
	PART 6 Alarm Systems					
54	How do you find the **auditory warnings** ?		4	**15**	14	2
55	How do you find the **visual warnings** ?		2	15	**17**	1
56	How clearly do you **understand** the **alarm caption**?		1	16	**17**	
57	How **visible** is the **alarm caption** ?		2	14	**16**	

Appendix

Number	Question	Unacceptable	Poor	Satisfactory	Good	Excellent
	PART 7 Patient Area					
58	How easy do you find it **to access the patient** ?	2	2	**11**	**11**	5
59	**What is your opinion of the :** **mattress size** ?		3	9	**17**	5
60	**mattress tilt mechanism** ?		1	10	**16**	7
61	**range of tilt** of the **mattress**?		1	11	**17**	5
62	**mattress** tray **withdrawal**?		3	**12**	11	8
63	**mattress rotation**		1	**12**	11	9
64	**security of the side panels**?		1	**15**	14	5
65	**suitability of the tubing ports**?	3	5	**12**	**12**	2
66	**suitability of hand ports**?	1	2	10	**17**	4
67	**security** of **canopy access doors** when in incubator mode?	1		14	**17**	3
68	**ease** of **performing X-rays?**	1	2	**13**	6	6
69	Do you **use** the **X-ray tray**?	Yes = 11				
	PART 8 Nursing and Medical Procedures					
	In Radiant Warmer mode					
70	How easy do you find it to **handle the infant** and provide **general patient care**?	1	2	7	**17**	7
71	How easy do you find it to **feed the infant**?	1	6	**11**	10	4
72	What is your opinion of the **ease of access** to the infant **for nursing procedures**?	1	2	11	**14**	6
73	**How easy is it to perform a medical examination** while the infant is in this unit?	1	2	7	**17**	5
	In Incubator mode					
74	How easy do you find it to **handle the infant** and provide **general patient care**?	1	4	12	**14**	5
75	How easy do you find it to **feed the infant**?	1	10	**13**	7	2
76	What is your opinion of the **ease of access** to the infant **for nursing procedures**?	1	5	10	**16**	4
77	**How easy is it to perform a medical examination** while the infant is in this unit?	1	2	11	**12**	6
	In either mode					
78	What is your opinion of the **operator comfort when** you are providing nursing and general care using this device ?	2	3	10	**16**	4
79	Please indicate your experience of **cleaning and disinfection** of the unit?			**8**	6	2

Appendix

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